

FEB 14 2003

510(k) Summary of Safety and Effectiveness

K023848

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|-----------------------------------|---|
| Device Name | Model 675GE-64 Peripheral Vascular Coil consisting of Model 665GE-64 Lower Extremity Flexible Array and Model 538GE-64 Medium General Purpose Flex Coil |
| Applicability | Compatible with GE Signa 1.5T MRI systems with Phased Array option |
| Reason for 510(k) | New indication for use |
| Classification Name | Magnetic Resonance Diagnostic Device |
| Device Classification Panel | Radiology |
| Device Classification Number | 892.1000 |
| Product Code | 90MOS |
| Common Name | Magnetic Resonance Imaging Coil |
| Proprietary Name | Model 675GE-64 Peripheral Vascular Coil consisting of Model 665GE-64 Lower Extremity Flexible Array and Model 538GE-64 Medium General Purpose Flex Coil |
| Establishment Registration Number | 2183683 |
| Address of MFG Facility | IGC-Medical Advances Inc. 10437 Innovation Drive Milwaukee, WI 53226 |
| Point of Contact | Anthony Dietzler Quality Assurance Engineering and Regulatory Affairs (414) 258-3808 Ext. 255 |
| Classification | Class II |
| Intended Uses | |
| Diagnostic Uses | 2D, 3D imaging, proton density, T1 and T2 weighted imaging. 2D, 3D time of flight, phase contrast imaging. |

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|----------------------------|---|--|
| Anatomic Regions | Vascular structures, soft tissue and musculo-skeletal structures in the lower extremities (mid-abdomen to mid-foot). Pediatric applications. | |
| Standards | | |
| Performance Standards | None Established under Section 514 | |
| Voluntary Safety Standards | UL 544 | Medical and Dental Equipment |
| | UL 94 | Tests for Flammability of Plastic Materials |
| | IEC 601-1 | General Safety Requirements for Medical Electrical Equipment |
| | CPAI-84 | Specification for Flame Resistant Material Used in Camping Tentage |

Overview

The Radiology Devices Panel considered potential concerns regarding the safe and effective operation of Magnetic Resonance Diagnostic Devices when they recommended reclassification to Class II on July 27, 1987. After reclassification, the FDA's Center for Devices and Radiological Health released a draft guidance document for the content and review of Magnetic Resonance Diagnostic Device premarket notification submissions that offered clarification of these concerns. The following is a summary of the information contained within this premarket notification that addresses these concerns:

The GE 1.5T Signa MRI system operated with the IGC-Medical Advances Peripheral Vascular Coil is substantially equivalent to the same system operated with the legally marketed predicate device listed in section 4.0, within the Class II definition of Magnetic Resonance Diagnostic Device with respect to the safety parameter action levels:

Safety Parameters

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|---|-----------|
| Maximum Static Magnetic Field: | No change |
| Rate of Magnetic Field Strength Change: | No change |
| RF Power Deposition: | No change |
| Acoustic Noise Levels: | No change |

Imaging Performance Parameters

| | |
|-----------------------------------|-----------|
| Specification Volume: | No change |
| Signal-to-Noise Ratio: | No change |
| Image Uniformity: | No change |
| Geometric Distortion: | No change |
| Slice Thickness and Gap: | No change |
| High Contrast Spatial Resolution: | No change |

General Safety and Effectiveness Concerns

The device contains instructions for use. It includes indications for use, precautions, cautions, contraindications, warnings and quality assurance testing. This information assures safe and effective use of the device.

Substantial Equivalence Summary

The GE 1.5T Signa MRI system operated with the IGC-Medical Advances Peripheral Vascular Coil addressed in this PMN, has the same intended use and technological characteristics as the same system operated with the identified legally marketed predicate devices. The use of this coil does not affect the GE Signa system safety parameter specifications.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2003

Mr. R. Jerry Frohlich
Manager, QA/RA
IGC Medical Advances, Inc.
10437 Innovation Drive
MILWAUKEE WI 53226

Re: K023848
Trade/Device Name: Model 675GE-64 Peripheral
Vascular Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance
diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: November 15, 2002
Received: November 19, 2002

Dear Mr. Frohlich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

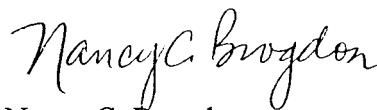
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|----------------------------------|----------------|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023848

Device Name: Model 675GE-64: Peripheral Vascular Coil

Indications for Use:

Magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) of adults and pediatrics of musculo-skeletal structures, soft tissue and vascular structures (mid-abdomen to mid-foot).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

David A. Leggett
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023848